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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/202,455	12/15/1998	KYOJI YAMAGUCHI	FJN-070	2918

7590 07/15/2002
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BOSTON, MA 02110

EXAMINER

HAMUD, FOZIA M

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 07/15/2002

25

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/202,455

Applicant(s)

Yamaguchi et al

Examiner

Fozia Hamud

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 3, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 69, 80, 84, 85, 87, and 90 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 69, 80, 84, 85, 87, and 90 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | 6) <input type="checkbox"/> Other: |

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DETAILED ACTION

1a. Receipt of Applicant's arguments and amendment filed on 03 May 2002 in Paper No:24 is acknowledged. Claims 82 and 88 have been canceled and claims 69 and 80 have been amended. Thus claims 69, 80, 84, 85, 87 and 90 are pending and under consideration.

Pending Claims:

1b. Applicants state that upon entry of the amendment filed on 03 May 2002, claims 69, 80, 84, 85, 87 and 90 are pending, (see remarks section of Applicants response). However, there is some confusion as to what claims are pending, because different numbering was used at different amendments. It appears that claims 69, 80, 84, 85, 87, 90 and 91 are pending. Claim 91 should be renumbered claim 90, since there were 90 claims (not 91) that were filed in the amendment of 18 August 2000 in Paper No:12. Claim 90 should be renumbered 87, because at the amendment filed on 29 March 2001, in Paper NO:14, claim 90 stands pending and is drawn to "The isolated nucleic acid of claims 80, wherein the protein encoded by said nucleic acid suppresses the biological activity of OCIF". Claim 87 should be renumbered 86 and then canceled. Then claims 69, 80, 84, 85, 87 and 90 will be pending.

2. The following previous objections and rejections are withdrawn in light of Applicants amendments filed in Paper No.24, 05/03/02:

- (i) All of the rejections of canceled claims 82 and 88 are withdrawn.
- (ii) The rejection of claims 69, 80, and 90 under 35 U.S.C. 102(e) as being anticipated by Anderson et al (US Patent 6,017,729), is withdrawn, because the claims do not recite the

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polynucleotides of SEQ ID NOs: 17 and 19, which shared 100% identity to the polynucleotide disclosed by Anderson et al.

(iii) The rejection of claims 80, 84-90 made under 35 U.S.C. 112, second paragraph, is also withdrawn.

3. ***Priority Dates:***

a) 09 7808/1997 filed on 04/15/97 discloses osteoclastogenesis inhibitory factor binding molecule (OBM) produced by mouse osteoblast stromal cell line ST2, therefore, only claims to OCIF binding protein would get the benefit of this foreign priority date.

b) 151434/1997 filed on 06/09/97 discloses mouse cDNA encoding OCIF binding molecule, and the full length mouse protein sequence. Claims drawn to mouse DNA are afforded this foreign priority date.

Claim Rejections - 35 U.S.C. § 102

4. Claims 69, 80, 84, 85, 87 and 90 are rejected under 35 U.S.C. 102(e) as being anticipated by Boyle (US Patent 5,843,678).

Boyle teaches an isolated murine nucleic acid molecule encoding a protein, that specifically binds to osteoprotegrin (OPG), an expression vector comprising said nucleic acid molecule and a method of making the encoded protein, (see column 3, lines 15-60, and Example 2). The protein disclosed by Boyle comprises 316 amino acid in length, has amino acid terminal, cytoplasmic domain, a transmembrane domain and a carboxyl terminal extracellular domain, and is involved in osteoclast differentiation, (see column 2, lines 20-55). The OPG binding protein disclosed by Boyle may be membrane-associated or may be in soluble form.

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The polynucleotide disclosed by Boyle shares 100% identity to instantly claimed polynucleotide sequence of SEQ ID NOs: 2,15 and 18 and encodes a polypeptide which shares 100% identity to the polypeptide of SEQ ID NOs:1 and 16 of the present invention. Therefore Boyle's reference clearly anticipates the instant claims 69, 80, 84, 85, 87 and 90.

This rejection was made in the office action mailed on 25 February 2000 in Paper NO:10, pages 12-14. In the response filed on 29 March 2001 in Paper NO:14, Applicants requested that the rejection over Boyle under 35 U.S.C. 102(e) be held in abeyance until all other rejections have been overcome. It appears that all other issues have been resolved and it is time that Applicants must respond to this rejection.

To clarify, priority dates, claim 69 is afforded the filing date of 09 7808/1997, which was filed on 04/15/97, because this Application discloses the protein and not the DNA encoding it. Claims 80, 84, 85, 87 and 90 are afforded the filing date of 151434/1997 which was filed on 06/09/97, because this document discloses mouse cDNA encoding OCIF binding molecule, and the full length mouse protein sequence. Therefore, claims drawn to mouse polynucleotide of SEQ ID NO:2 encoding the polypeptide of SEQ ID NO:1, and recombinant production of said polypeptide get the benefit of this priority date (i.e 06/09/97). Applicants argue that their earliest effective priority is to Japanese Patent Application 97808/1997 filed on 04/15/97, however, this document discloses only osteoclastogenesis inhibitory factor binding molecule (OBM) produced by mouse osteoblast stromal cell line ST2, therefore, claims drawn to isolated polynucleotide of SEQ ID NO:2, encoding SEQ ID NO:1, would not get the benefit of the priority date of 04/15/97 but rather 06/09/97.

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In any event, the Boyle Patent is still 102(e) for all of the pending claims, because the effective filing date of the Boyle Patent Application is 17 April 1997.

Conclusion

5. No claim is allowed.
6. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday-Thursday from 8:00AM to 4:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Fozia Hamud
Patent Examiner

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03 July 2002

Gary L. Kunz
GARY L. KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600